

WHAT IS CLAIMED IS:

1. A pharmaceutical composition for use in preventing and treating graft-versus-host disease (GVHD) and host-versus-graft disease (HVGD) comprising a pharmaceutically acceptable carrier and at least one copolymer selected from the group consisting of random copolymers comprising one amino acid selected from each of at least three of the following groups:

- (a) lysine and arginine;
- (b) glutamic acid and aspartic acid;
- (c) alanine and glycine;
- (d) tyrosine and tryptophan,

with the proviso that the random copolymer is not Copolymer 1 or D-Copolymer 1 when the disease being treated is graft-versus-host disease.

2. The pharmaceutical composition according to claim 1, wherein the copolymer contains four different amino acids each from one of the groups (a) to (d).

3. The pharmaceutical composition according to claim 2, wherein the copolymer comprises in combination alanine, glutamic acid, lysine, and tyrosine, of net overall positive electrical charge and of a molecular weight of about 2,000 to about 40,000 daltons.

4. The pharmaceutical composition according to claim 3, wherein the copolymer has a molecular weight of about 2,000 to about 13,000 daltons.

5. The pharmaceutical composition according to claim 4 for use in preventing and treating host-versus-graft disease (HVGD), wherein the copolymer is Copolymer 1 of average molecular weight of about 4,700 to about 13,000 daltons.

6. The pharmaceutical composition according to claim 1, wherein the copolymer contains three different amino acids each from one of three groups of the groups (a) to (d), herein referred to as terpolymers.

7. The pharmaceutical composition according to claim 6, wherein the random terpolymer consists essentially of the amino acids tyrosine, alanine and lysine.

8. The pharmaceutical composition according to claim 7, wherein the terpolymer consists of tyrosine, alanine and lysine, in the molar ratio of from about 0.005 to about 0.25 tyrosine, from about 0.3 to about 0.6 alanine, and from about 0.1 to about 0.5 lysine, herein designated YAK.

9. The pharmaceutical composition according to claim 6, wherein the random terpolymer consists essentially of the amino acids glutamic acid, tyrosine, and lysine.

10. The pharmaceutical composition according to claim 9, wherein the random terpolymer consists essentially of the amino acids glutamic acid, tyrosine, and lysine in the molar ratio of from about 0.005 to about 0.300 glutamic acid, from about 0.005 to about 0.250 tyrosine, and from about 0.3 to about 0.7 lysine, herein designated YEK.

11. The pharmaceutical composition according to claim 6, wherein the random terpolymer consists essentially of the amino acids tyrosine, glutamic acid, and alanine.

12. The pharmaceutical composition according to claim 11, wherein the random terpolymer consists essentially of the amino acids tyrosine, glutamic acid, and alanine in the molar ratio of from about 0.005 to about 0.25 tyrosine, from about 0.005 to about 0.3 glutamic acid, and from about 0.005 to about 0.8 alanine, herein designated YEA.

13. The pharmaceutical composition according to claim 6, wherein the random terpolymer consists essentially of the amino acids glutamic acid, alanine and lysine.

14. The pharmaceutical composition according to claim 13, wherein the random terpolymer consists essentially of the amino acids glutamic acid, alanine and lysine in the molar ratio of from about 0.005 to about 0.3 glutamic acid, from about 0.005 to about 0.6 alanine, and from about 0.2 to about 0.7 lysine, herein designated KEA.

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15. The pharmaceutical composition according to any one of claims 1 to 14, wherein the amino acids comprising the copolymers are all L-, all D- or a mixture of L- and D-amino acids.

16. A method for treating or preventing graft-versus-host disease (GVHD) or host-versus-graft disease (HVGD) in a mammal comprising administering a therapeutically effective amount of an active ingredient selected from the group consisting of random copolymers comprising one amino acid from at least three of the following groups, the groups consisting of:

- (a) lysine and arginine;
- (b) glutamic acid and aspartic acid;
- (c) alanine and glycine;
- (d) tyrosine and tryptophan;

with the proviso that the random copolymer is not Copolymer 1 or D-Copolymer 1 when the disease being treated is graft-versus-host disease.

17. The method according to claim 16, wherein the copolymer contains four different amino acids each from one of the groups (a) to (d).

18. The method according to claim 17, wherein the copolymer comprises in combination alanine, glutamic acid, lysine, and tyrosine, of net overall positive electrical charge and of a molecular weight of about 2,000 to about 40,000 daltons.

19. The method according to claim 18, wherein the copolymer has a molecular weight of about 2,000 to about 13,000 daltons.

20. The method according to claim 19 for preventing and treating host-versus-graft disease (HVGD), wherein the copolymer is Copolymer 1 of average molecular weight of about 4,700 to about 13,000 daltons.

21. The method according to claim 16, wherein the copolymer contains three different amino acids each from one

of three groups of the groups (a) to (d), herein referred to as terpolymers.

22. The method according to claim 21, wherein the random terpolymer consists essentially of the amino acids tyrosine, alanine and lysine.

23. The method according to claim 22, wherein the terpolymer consists of tyrosine, alanine and lysine, in the molar ratio of from about 0.005 to about 0.25 tyrosine, from about 0.3 to about 0.6 alanine, and from about 0.1 to about 0.5 lysine, herein designated YAK.

24. The method according to claim 21, wherein the random terpolymer consists essentially of the amino acids glutamic acid, tyrosine, and lysine.

25. The method according to claim 24, wherein the random terpolymer consists essentially of the amino acids glutamic acid, tyrosine, and lysine in the molar ratio of from about 0.005 to about 0.300 glutamic acid, from about 0.005 to about 0.250 tyrosine, and from about 0.3 to about 0.7 lysine, herein designated YEK.

26. The method according to claim 21, wherein the random terpolymer consists essentially of the amino acids tyrosine, glutamic acid, and alanine.

27. The method according to claim 26, wherein the random terpolymer consists essentially of the amino acids tyrosine, glutamic acid, and alanine in the molar ratio of from about 0.005 to about 0.25 tyrosine, from about 0.005 to about 0.3 glutamic acid, and from about 0.005 to about 0.8 alanine, herein designated YEA.

28. The method according to claim 21, wherein the random terpolymer consists essentially of the amino acids glutamic acid, alanine and lysine.

29. The method according to claim 28, wherein the random terpolymer consists essentially of the amino acids glutamic acid, alanine and lysine in the molar ratio of from about 0.005 to about 0.3 glutamic acid, from about 0.005 to

about 0.6 alanine, and from about 0.2 to about 0.7 lysine, herein designated KEA.

30. The method according to any one of claims 16 to 29, wherein the amino acids comprising the copolymers are all L-, all D- or a mixture of L- and D-amino acids.

31. The method according to any one of claims 16 to 30, wherein said patient receives a transplanted organ or tissue.

32. The method according to claim 31, wherein said patient receives an HLA matched or unmatched transplant.

33. The method according to ~~claim~~ 31 or 32, wherein said organ or tissue is any one of heart, lung, kidney, liver, bone marrow or skin.

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